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ORIGINAL RESEARCH

To compare the diagnostic accuracy of BIRADS score with histopathological findings in breast lump

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Abstract

Background: Given that breast cancer is the most common cancer in women worldwide and the leading cause of death for cancer patients, women who develop breast lumps need to be properly assessed and diagnosed. The prevalence of breast cancer is rising in India, where it has surpassed cervical cancer in all metropolitan cancer registries to become the most frequent cancer among women.Women with clinically examined breast lumps or suspicious symptoms are typically subjected to imaging tests such as mammography and ultrasound. Preoperative histopathological diagnosis and mammography (using breast imaging reporting and data system (BI-RADS) scoring system) constitute an essential part of the workup of breast lesions.The present study was aimed to compare the diagnostic accuracy of BIRADS score with histopathological findings in breast lump.

Methods: This is prospective observational studyconducted on 104 patients with clinical or suspected breast lump attended out patient department(OPD) or admitted to Sri guru Ramdas hospital in the department of General surgery attached to Sri guru Ramdas university of health sciences and research,Sri amritsar.

Results: Considering histopathological examination as gold standard, the sensitivity and specificity of BI-RADS score is 93.75% and 75% respectively. The positive predictive value, negative predictive value and diagnostic accuracy of BI-RADS score is 97.83%, 50% and 92.31% respectively.

Conclusion: The study demonstrates that In cases of breast lumps, the diagnostic accuracy of BIRADS scoring must be considered in light of its advantages and disadvantages. While BIRADS provides a standardized framework for reporting breast imaging findings and guiding management decisions, it is not without limitations, including subjectivity, the potential for false results, and the inability to provide tissue diagnosis so BIRADS score cannot be used as an alternative to histopathology in diagnosis of breast lump. Therefore, BIRADS scoring should be used judiciously, with awareness of its strengths and weaknesses, and findings should be confirmed with histopathology when appropriate to ensure accurate diagnosis and optimal patient care.

Keywords: BIRADS score,breast lump, histopathology(excision/trucut biopsy)

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Introduction

The most prevalent cancer and the second largest cause of cancer-related mortality for adult women is breast cancer. Over 2 million new cases of breast cancer are diagnosed globally each year, and this number is growing.[1]

Given that breast cancer is the most common cancer in women worldwide and the leading cause of death for cancer patients, women who develop breast lumps need to be properly assessed and diagnosed. Breast cancer ranks second among cancers that affect women in India. Moreover, its mortality rate is 12.7 per 100,000 individuals, and its age-adjusted incidence in women is 25.8 per 100,000 individuals.[2]

The prevalence of breast cancer is rising in India, where it has surpassed cervical cancer in all metropolitan cancer registries to become the most frequent cancer among women.[3]

The GLOBOCAN 2018 report states that the age-standardized rate for this disease is 31 per 100,000 people. Thus, it is important to recognize that early detection of breast cancers can influence their prognosis in this nation. Women who have clinically examined breast masses or suspicious symptoms are typically subjected to imaging tests such as mammography and ultrasound. The primary non-invasive imaging modalities used to assess breast abnormalities are these ones. Breast masses can be screened for and diagnosed with mammography. Lastly, pathological evaluations are required for suspicious imaging results in order to make a definitive diagnosis.[4]

Collaboration between radiologists and pathologists appears necessary in the evaluation of the consistency of radiologic and pathological findings, given the rising number of newly diagnosed cases in breast imaging. This will ensure that the right and appropriate approach is taken into consideration. The American College of Radiology created the breast imaging-reporting and data system (BI-RADS), a standardized format and terminology in this regard. The most crucial component of an imaging report is BI-RADS. Under this system, an explanation of the breast's general composition ought to open every report. The higher number in BI-RADS's seven categories, which range from 0 to 6, indicates malignancy.There is a dearth of research on the precision of mammography and ultrasonography, as well as their BI-RADS classification, in distinguishing between benign and malignant breast masses.[5]

Given the appalling situation and high death rate associated with breast cancer, particularly in developing countries, the standard of assessment provided by diagnostic services for female breast cancer patients has to be raised. As a result, a suitable assessment is necessary, which includes obtaining a thorough medical history, performing a breast exam, using imaging, and diagnosing cytology or tissue. Failing to do so could result in treatment decisions that are not appropriate.[6]

While the histopathological results of tissues are the basis for the final diagnosis, it is not practical to remove or biopsy every breast lump. Therefore, early diagnostic techniques—like mammography and fine needle aspiration—are crucial because they are easy to use, quick, safe, and presumptive. They also save unnecessary testing and procedures, which benefits patients and clinicians by facilitating appropriate preoperative diagnosis and management.[6]

Since fine needle aspiration cytology (FNAC) offers a quick, precise, and affordable diagnosis, it is still commonly used in India to evaluate breast masses in both palpable and non-palpable lesions. But when it comes to evaluating breast lesions, FNAC has a lot of drawbacks that result in an excessive number of excision biopsies being performed to diagnose breast masses,also FNAC is less reliable for differentiating between in situ and invasive cancers."[7]

For symptomatic and screen-detected breast lesions, core biopsy has mostly replaced fine needle aspiration in western countries. When compared to excision or incision biopsy for

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diagnosis, it is far less invasive and costly, and the frequency of nondiagnostic or inadequate sample reports is lower than that of FNAC.[8]

Because it accurately depicts the nature of lesions, radiologists, treating physicians, and surgeons can use it to aid in particular diagnosis and treatment plans. On the other hand, it has been estimated that between 4% and 12% of false-negative cases result from mammography findings of a palpable breast mass. Consequently, even in cases where mammography results indicating a palpable mass indicate benign or borderline lesions, malignancy cannot be ruled out.[9]

Sometimes excision biopsy Is preferred over trucut biopsy or FNAC when these less invasive methods are inconclusive or when the lump is small and can be entirely removed, trucut biopsy and FNAC are generally diagnostic only whereas excision biopsy can serve as both a diagnostic and therapeutic procedure.[10]

Over the past few decades, significant advancements in the field of medicine have been made in the early detection of breast cancers through the use of various imaging techniques, including mammography, ultrasound, and breast magnetic resonance imaging (MRI). Breast disease can be diagnosed clinically through self-breast assessment and routine clinical check-ups. But the majority of early-stage breast cancers are occult, and clinical methods are inadequate for properly evaluating them.

Because mammography is readily available, widely accepted, and reasonably priced, it is the main imaging modality used to screen for and diagnose breast cancer. The American College of Radiology (ACR) published and trademarked the Breast Imaging-Reporting and Database System (BI-RADS) score in the late 1980s as a solution to the issue of non-uniformity in mammography reporting. The system was developed through the collaborative efforts of numerous health groups in the United States of America. Its most recent edition, the fifth, was published in 2013 and includes seven categories, numbered 0 through 6.

When evaluating a breast mass, the surgeon's primary responsibility is to conduct a thorough, effective, and timely consultation to allay concerns, rule out cancer, and, in the event that cancer is found, provide an accurate diagnosis and suitable treatment plan. While not all breast lumps are cancerous and not all benign lumps become malignant, the accuracy of the final diagnosis can be significantly improved by employing triple assessment, which combines clinical examination, radiological imaging (ultrasonography, mammography), and pathological diagnosis. The American College of Radiology created the Breast Imaging Reporting and Data System (BIRADS) lexicon to facilitate interdisciplinary standardization in communication between radiologists and surgeons. It also enables the correlation of radiological and pathological findings related to a breast lump, enabling precise diagnosis and treatment planning.

In order to assess the reliability of BI-RADS (Breast Imaging Reporting and Data System), which may prevent needless aggressive interventions for typically benign lesions or may alert to perform surgical intervention for malignancy on time, the current study aims to assess the diagnostic accuracy of BI-RADS by using radiological procedures like ultrasound with histopathological findings in the diagnosis of benign and malignant lumps.

Our investigation aims to assess the relationship between the BIRADS categories and the histopathology classification of breast lumps.

In order to determine the sensitivity, specificity, positive, and negative predictive values of BIRADS scoring in predicting malignancy, a correlation between the BIRADS Score and the histopathological finding in women presenting to our institute with breast lumps is the aim of this study.[11]

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Materials and methods

Study area

General Surgery department, Sri Guru Ram Das University of Medical science and research

Study group

Patients who clinically presented with breast lesions attended out-patient department (OPD) or admitted to Sri Guru Ram Das Hospital attached to Sri Guru Ram Das Institute of Medical Sciences and Research, Sri Amritsar were included in the study.

Sample Size/Study period

This Study was conducted on 104 patients presented or admitted with clinical or suspected breast lump under a period from 01st January to 31st March 2024.

Inclusion criteria

Women with breast lump willing to undergo sonomammogram and trucut/excision biopsy of breast lump.

Methodology

- Females with clinical or suspected breast lump presented in the surgery OPD or admitted to Sri guru ram das hospital in the surgery department were included in the study.
- The women were examined after having appropriate history of lump or nipple discharge and advised sonomammography for detecting lesions.
- Suspicion of breast cancer on BI-RADS mammogram was considered for categories 2-5 from either site of breast while category-1 was considered negative

Later on biopsy (trucut/Excision) of the lesions was done to confirm the findings of mammography according to the newly introduced BIRADS classification using histopathological study as gold standard criteria

Results

Table no 1: Age Group wise distribution of patients

Age Group	Frequency	Percentage
<=20	4	3.8
21-40	26	25.0
41-60	55	53.8
>60	18	17.3
Total	104	100.0

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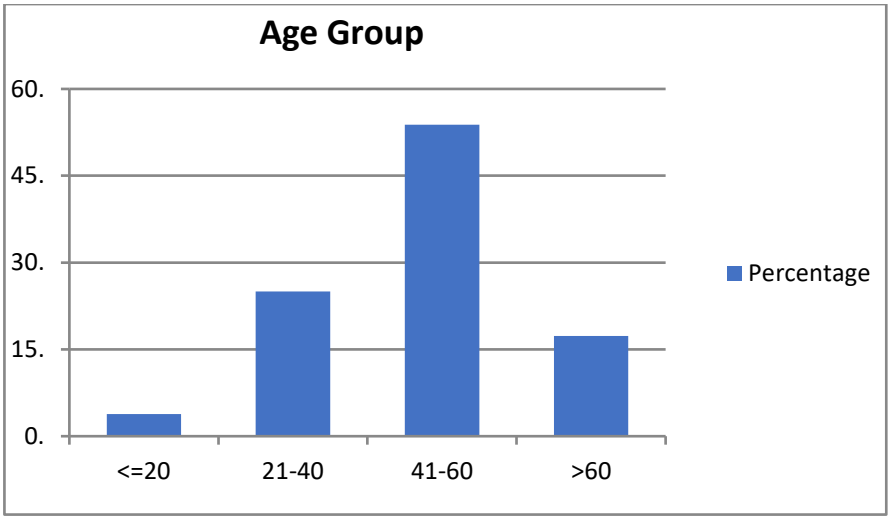

The table no 1 shows age group of the patients. The patients who are less than 20 years, were 3.8%, 21 to 40 years were 25%. 41 to 60 years were 53.85, and more than 60 years were 17.3%.

Table no 2: **patient distribution according to BIRADS category**

BIRAD Score	Frequency
BIRAD 2	3
BIRAD 3	9
BIRAD 4	59
BIRAD 5	33
Total	104

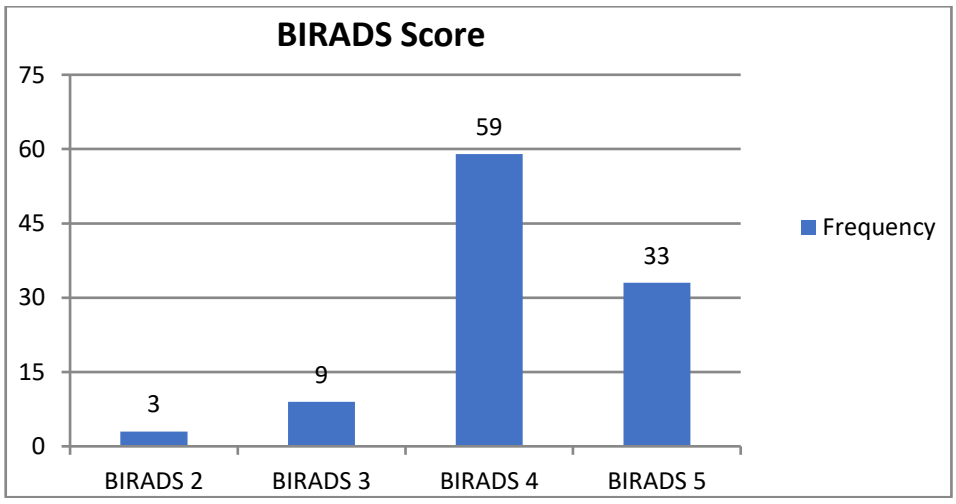

Table 2. BIRADS 2 was found in 3, BIRADS 3 was found in 9, BIRADS 4 was found in 59, BIRADS 5 was found in 33 patients.

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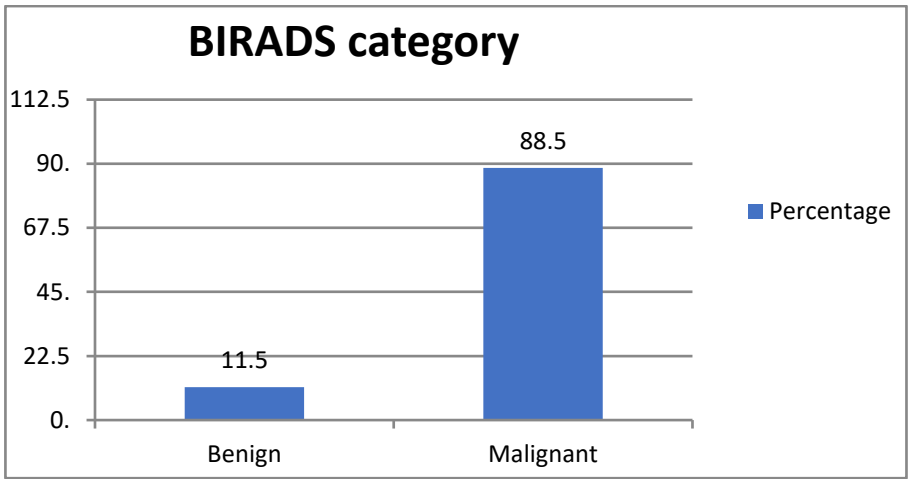
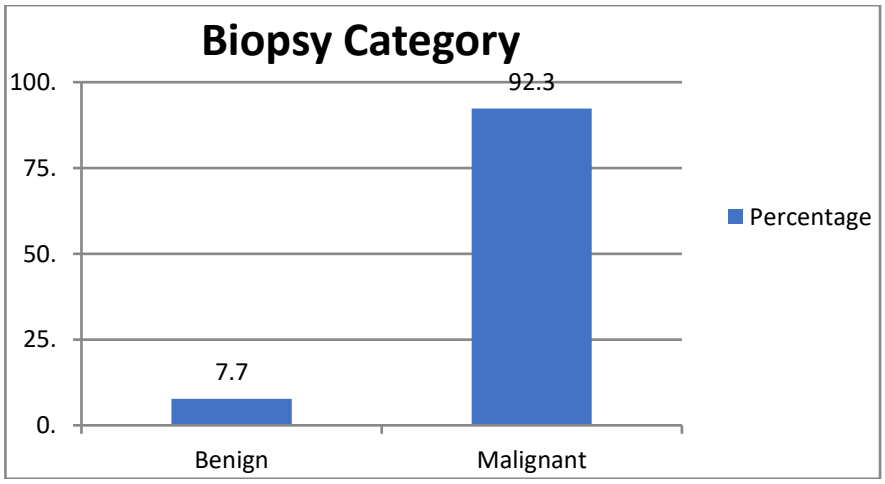
BIRAD Category	Frequency	Percentage
Benign	12	11.5
Malignant	92	88.5
Total	104	100.0



Considering BI-RADS score 1, 2 and 3 to be benign and score of 4, 5 and 6 to be malignant, it was seen that 12 cases out of 104 (11.5%) were benign and 92 cases out of 104 (88.5%) were malignant.

Table no 3: Patient distribution according to Biopsy Category

Biopsy Category	Frequency	Percentage
Benign	8	7.7
Malignant	96	92.3
Total	104	100.0



The table no 3 shows distribution according to Biopsy category. The patients who were benign were 7.7%, and malignant were 92.3%.

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TABLE NO 4: Comparison between BIRADS category and Biopsy category

		Biopsy Category			P value
BIRAD Category		**Benign**	**Malignant**	**Total**	.000
Benign	Count	6	6	12	
Malignant	Count	2	90	92	
Total	Count	8	96	104	

True Positive	False Positive	True Negative	False Negative	n	Sensitivity (%)	Specificity (%)	Positive Predictive Value (%)	Negative Predictive Value (%)	Accuracy (%)	LR+	LR-	Youden's Index
90	2	6	6	104	93.75	75.00	97.83	50.00	92.31	3.750	0.08	68.75

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	34.196[a]	1	.000		
Continuity Correction[b]	27.792	1	.000		
Likelihood Ratio	20.501	1	.000		
Fisher's Exact Test				.000	.000
Linear-by-Linear Association	33.867	1	.000		
N of Valid Cases	104				

a. 1 cells (25.0%) have expected count less than 5. The minimum expected count is .92.

b. Computed only for a 2x2 table

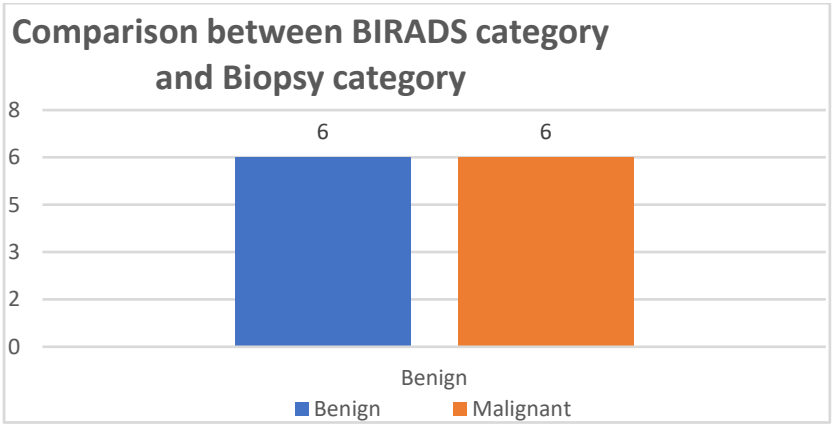

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Table no 4 shows relationship between BIRAD category and biopsy category. The cases with BIRAD category benign, out of them 6 were benign biopsy cases and 6 were malignant biopsy cases. And for the cases whose BIRADS category was malignant, there were 2 benign biopsy cases and 90 malignant biopsy cases.

Discussion

Age Distribution of Patients

In our study, it was observed that among benign cases, 4(3.85%) cases were less than 20 years of age, 4 (3.85%) cases were between 21-40 years, while among malignant cases, 55 (52.8%) cases were between 41-60 years, 18(17.3%) cases were >60 years, 22 (21.1%) cases were between 21-40years.

Benign Breast Lumps:

1. Young Age Prevalence:

A notable observation is that 50% of the benign cases are found in individuals less than 20 years old. This suggests a higher prevalence of benign breast lumps in younger individuals. The remaining 50% of benign cases occur in the 21-40 age group, indicating that benign lumps are relatively common in younger adults but less so as age increases.

2. Implications:

These findings align with the understanding that benign breast conditions, such as fibroadenomas, are more frequently diagnosed in younger women. This can be attributed to hormonal changes and the development phase of breast tissue in this age group.

Malignant Breast Lumps:

1. •Age-Related Increase:

Malignant breast lumps show a clear trend of increasing prevalence with age. The majority of cases (57%) are found in the 41-60 age group. There is still a significant number (23%) of cases in the 21-40 age group, indicating that breast cancer is not rare among younger adults, though less common compared to older age groups.

• 18 patients (19%) are over 60 years old, highlighting that breast cancer risk continues to increase with age.

2. Implications:

This distribution underscores the importance of regular breast cancer screening and awareness across all age groups, but particularly emphasizes the increased risk and need for vigilance in older patients.

The age distribution in our study reveals that the majority of patients with breast lumps were aged 41-60 years (52.8%), which aligns with findings by Devolli et al.. Devolli et al. observed that age and breast density substantially influenced the sensitivity of diagnosing breast conditions. Our study found a lower prevalence of breast lumps in younger patients, with those aged 20 years or less comprising only 3.8% of the cases. This observation is consistent with the lower sensitivity of mammography for younger women reported by Devolli et al. This underscores the importance of considering age and breast density in diagnostic imaging. Older age groups have a higher risk of malignancy, emphasizing the need for targeted screening and vigilant monitoring, particularly for middle-aged and older women.[46]

BIRADS Category Distribution

In the present study, it was observed that 12 (11.5%) cases were having benign lump while 92 (88.5%) cases were having malignant lump on BI-RADS score.

Distribution analysis:

BIRADS 2 and 3:

- 12 patients (approximately 11.54% of the total)

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- These categories represent cases with a high likelihood of benign findings.
- Clinical Implications:
  - Patients in these categories typically require less aggressive intervention.
  - BIRADS 3 patients might need follow-up imaging to confirm stability over time, while BIRADS 2 patients usually need routine screening.[47, 48,49]

BIRADS 4 and 5:

- 92 patients (approximately 88.46% of the total)
- These categories are associated with a higher suspicion of malignancy, necessitating further diagnostic procedures like biopsies.
- Clinical Implications: A significant proportion of patients fall into these categories, indicating a high prevalence of suspicious or malignant lesions.
- BIRADS 4 patients may have varying degrees of suspicion, requiring careful assessment to determine the necessity and type of biopsy.
- BIRADS 5 patients are very likely to have malignancy, leading to more definitive diagnostic and therapeutic intervention.

In our study, 88.5% of the patients were found to have malignant lumps based on BI-RADS categorization. This is consistent with Chavan SG et al. (2020), who reported high sensitivity (93.9%) and specificity (82.3%) of the BI-RADS score in diagnosing breast lump lesions. Although BI-RADS is a valuable non-invasive tool, our findings, similar to those of Chavan SG et al. (2020), suggest that histopathological examination remains essential for definitive diagnosis. This highlights the critical role of accurate imaging techniques in early detection and timely intervention.[11]

Biopsy Category Distribution

In this study involving 104 patients with breast lumps, biopsy results categorized the lumps into benign and malignant cases:

- Benign cases: 8 patients
- Malignant cases: 96 patients

Distribution Analysis:

Benign Cases:

- 8 out of 104 patients (approximately 7.69%)
- These cases represent non-cancerous findings upon biopsy.
- Clinical Implications:

Benign breast lumps often include conditions such as fibroadenomas, cysts, and other non-malignant growths.

- Management typically involves regular monitoring and follow-up imaging, with surgical removal considered if the lumps are symptomatic or cause significant concern for the patient.

Malignant Cases:

- 96 out of 104 patients (approximately 92.31%)

These cases are diagnosed as cancerous upon biopsy.

- Clinical Implications:

The high percentage of malignant cases indicates a significant prevalence of breast cancer. Immediate and comprehensive treatment plans, including surgery, chemotherapy, radiation therapy, and hormone therapy, may be necessary depending on the type and stage of cancer.

This high rate of malignancy underscores the importance of early detection and aggressive diagnostic measures.

Our biopsy results revealed that 92.3% of patients had malignant outcomes, reinforcing the importance of biopsy as a definitive diagnostic tool, as emphasized by GN et al. (2021). GN et al. reported similar findings, with a nearly equal distribution of benign and malignant

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masses, and noted that combined mammography and ultrasound had a higher accuracy rate than either technique alone. This underscores the necessity of integrating multiple diagnostic modalities to ensure precise identification and management of breast lumps.[31]

BIRADS and Biopsy Category Correlation

In our study, it was seen that 6 cases were benign on both HPE and BI-RADS score, 2 case was benign on HPE and malignant on BI-RADS score while 6 cases were malignant on HPE and benign on BI-RADS score and 90 cases were malignant on both HPE and BI- RADS score. Considering HPE as gold standard, the sensitivity and specificity of BI-RADS score is 93.75% and 75% respectively. The positive predictive value, negative predictive value and diagnostic accuracy of BI- RADS score is 97.83%, 50% and 92.31% respectively.

In the study conducted by Chavan SG et al. (2020), it was seen that 62 cases were benign on both HPE and BI-RADS score, 4 case was benign on HPE and malignant on BI-RADS score while 6 cases were malignant on HPE and benign on BI-RADS score and 28 cases were benign on both HPE and BI- RADS score. Considering HPE as gold standard, the sensitivity and specificity of BI-RADS score is 93.9% and 82.3% respectively. The positive predictive value, negative predictive value and diagnostic accuracy of BI- RADS score is 91.1%, 87.5% and 90.0% respectively.

The high level of concordance between BI-RADS scores and biopsy outcomes in our study, with occasional discrepancies, is consistent with GN et al. (2021), who reported that the BI-RADS classification demonstrated respectable positive predictive values. Our findings highlight the reliability of BI-RADS in predicting malignancy while emphasizing the necessity of biopsy for confirmation, as also noted by Chavan SG et al. (2020)[11] and GN et al. (2021).[31]

Among the 104 patients, there were 3 cases where lesions classified as BIRADS 2 were found to be malignant upon histopathological examination. BIRADS 2 typically indicates benign findings, suggesting that there is no suspicion of malignancy. The occurrence of malignancy in these cases raises concerns about the sensitivity and specificity of the BIRADS system. The unexpected finding of malignancy in BIRADS 2 cases affects the NPV of the BIRADS system. Typically, BIRADS 2 is associated with a very high NPV, but these false-negative results (where the BIRADS category underestimated the malignancy risk) suggest that while BIRADS is a useful tool, it is not infallible.

This detailed analysis highlights several critical aspects of breast lump diagnosis and management, emphasizing the importance of age, imaging techniques, biopsy, and tailored treatment strategies. The findings advocate for early detection, accurate diagnosis, and personalized treatment to improve breast cancer management and patient outcomes, consistent with the insights provided by Devolli et al. (2009),[46] Sohns C et al. (2011)[21], Chavan SG et al. (2020),[11] GN et al. (2021),[31] and Aklilu S et al. (2021). By integrating these diverse approaches, we can enhance the accuracy and efficacy of breast cancer diagnostics and treatment, ultimately leading to better patient care and outcomes.

Conclusion

The study demonstrates that BIRADS scoring is a highly effective tool for the initial evaluation of breast lumps, with a high diagnostic accuracy, sensitivity, and PPV. These metrics indicate that BIRADS is particularly reliable in identifying malignant lumps and confirming malignancy. However, the lower NPV and moderate specificity suggest that benign findings from BIRADS should be carefully considered and often verified with additional diagnostic methods, such as histopathology. This combined approach ensures comprehensive and accurate diagnosis, optimizing patient management and reducing the risk of misdiagnosis.

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In cases of breast lumps, the diagnostic accuracy of BIRADS scoring must be considered in light of its advantages and disadvantages. While BIRADS provides a standardized framework for reporting breast imaging findings and guiding management decisions, it is not without limitations, including subjectivity, the potential for false results, and the inability to provide tissue diagnosis so BIRADS score cannot be used as an alternative to histopathology in diagnosis of breast lump. Therefore, BIRADS scoring should be used judiciously, with awareness of its strengths and weaknesses, and findings should be confirmed with histopathology when appropriate to ensure accurate diagnosis and optimal patient care.

Conflict of interest

There is no conflicts of interest.

Source of funding

NIL

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